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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/993,168	11/06/2001	Merrit N. Jacobs	CDS-256	8482

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EXAMINER
FOSTER, CHRISTINE E

ART UNIT	PAPER NUMBER
1641	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/993,168	JACOBS ET AL.	
	Examiner	Art Unit	
	Christine Foster	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 September 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21,22,24,25 and 30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21,22,24,25 and 30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *11/16/01* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Amendment Entry

1. Applicant's amendment, filed 9/18/07, is acknowledged and has been entered. Claim 21 has been amended. Accordingly, claims 21-22, 24-25, and 30 are currently pending and under examination.

Objections/Rejections Withdrawn

2. The objection to claim 21 is withdrawn in response to Applicant's amendments thereto.

3. The objections to the Drawings as set forth in the previous Office action were in error and are withdrawn in response to Applicant's arguments (Reply, page 7).

4. The rejections of claims 21-22, 24-25 and 30 under § 112, 1st paragraph as containing new matter are withdrawn in response to Applicant's amendments to claim 21. However, new grounds of rejection under this statute are set forth below in light of the amended claims.

5. The rejections under § 112, 2nd paragraph not reiterated below have been withdrawn.

Priority

6. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

Benefit claims under 35 U.S.C. 120, 121, and 365(c) must identify the prior application by application number *and indicate the relationship between the applications*. See 37 CFR 1.78(a)(2)(i).

Applicant's preliminary amendment of 11/6/01 identified the instant application as a divisional of prior application No. **09/510,928** in the first paragraph of the specification. In the previous Office action, Applicant was requested to update this reference to reflect that the prior application has now matured into U.S. patent No. 6,651,993.

However, Applicant has now amended the first paragraph of the specification such that the relationship to this prior application (i.e., as a *divisional* application) is no longer indicated. In order to obtain the benefit of the prior-filed application, Applicant must specify whether the application is a continuation, divisional, or continuation-in-part of the prior application.

In addition, the instant amendment also includes a new reference to prior application No. **09/993,054**. However, the relationship to this prior application is also not indicated. Accordingly, the benefit claim does not comply with 35 U.S.C. 120 and 37 CFR 1.78(a)(2)(i) since the proper relationship, which includes the type of continuing (i.e., continuation, divisional, or continuation-in-part) application, is not stated.

See MPEP 201.11.

Specification

7. The amendment filed 9/18/07 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows:

8. The replacement abstract includes the concluding sentence "A strong agglutination reaction occurs when the absorbance by said mixture decreases to about zero when sixty five

percent of the volume of the mixture has been scanned, when the first cavity is above the second cavity", which represents new matter for the reasons detailed in the § 112, 1st paragraph rejection immediately below.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 21-22, 24-25, and 30 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. *This is a new matter rejection.*

Claim 21, as amended in the Reply of 9/18/07, recites step (g) of determining the strength of agglutination, "wherein a strong agglutination reaction occurs when the absorbance by said mixture decreases to about zero when sixty five percent of the volume of the mixture has been scanned, when the first cavity is above the second cavity".

Applicant's Reply does not indicate where the amendments are supported by the specification, and support could not be found by the Examiner for the following reasons.

The specification discloses on page 18, the first full paragraph that:

> A strong reaction clumps the red cells so well that after about 65%, the volume is essentially free of cells and is clear. A weak reaction has less absorption, but still much more than the strong, after 65% of the volume scanned.

This passage does not adequately support the subject matter now claimed. The indicated passage relates only to agglutination of *red blood cells* as assessed using an illuminating wavelength of 540 nm, while the instant claims are relate to any type of agglutinated material. As such, the claims broaden the scope of the disclosure and therefore represent new matter. In particular, there is no indication that the observation of agglutinated red blood cells passing into the second cavity within the first 65% of the sample volume would also hold true for all agglutination reactions. Since the sedimentation rate of other agglutinated materials (e.g., an antigen being agglutinated by antibody binding) would be expected to differ from that of red blood cells, one skilled in the art would not expect the precise value of 65% to be universal for all agglutination reactions.

11. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

12. Claims 21-22, 24-25, and 30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

13. Claim 21 as amended now recites that "a strong agglutination reaction occurs when the absorbance by said mixture decreases to about zero when sixty five percent of the volume of the mixture has been scanned, when the first cavity is above the second cavity" in part (g), which is indefinite because it fails to clearly define how the strength of the agglutination reaction is assessed.

In particular, the claim refers to a decrease in absorbance. This implies multiple measurements; i.e. that the absorbance is being monitored continuously over time or that the absorbance is measured at different time points. What is the decrease in absorbance being measured relative to? The first detection step (d) that is performed? The initial absorbance of the sample? The claim fails to clearly set forth any steps in which multiple measurements of the absorbance are taken at different time points, such that the reference to "when the absorbance by said mixture decreases to about zero" cannot be clearly interpreted.

In addition, the claim refers to "when sixty five percent of the volume of the mixture has been scanned", which suggests that not all of the sample is scanned at once. However, the claim fails to clearly recite any steps in which a percentage of the mixture is scanned. As such, the recitation renders the claim indefinite there are no corresponding active methods steps in which only a percentage of the volume of the mixture is scanned.

In addition, the claim now concludes with "when the first cavity is above the second cavity", which is indefinite because it is unclear what method steps and/or structural limitations are being invoked by this terminology. In particular, the placement of this limitation as part of the conclusion step, which describes how the results of the method are assessed, might cause this limitation to be interpreted as meaning that *scanning* occurs with the first cavity positioned above the second cavity, but that at other times, this spatial relationship might not apply. In other words, the reference to "when the first cavity is above the second cavity" might be construed as implying that the probe tip is inverted during the method and that there are times when this is not the case. This interpretation is also conveyed in the use of the conjunction "when", which implies a time component.

Alternatively, the limitation could also be construed as structural limitation of the probe tip—i.e., that the tip is constructed with the first cavity above the second cavity. If Applicant intends to convey such a meaning, it is suggested the limitation would be more appropriately introduced in part (b) (where the second cavity is first described) rather than in part (g). For example, part (b) could conclude with --*wherein* the first cavity is above the second cavity--.

For all of these reasons, the conclusion step recited in part (g) renders the claim indefinite because the step invokes subject matter that cannot be clearly correlated with the method steps earlier recited in the claim. As such, it is unclear how the strength of the agglutination reaction is being determined.

14. Claim 21 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: the other component of the agglutination reaction.

The claim refers to an "agglutination reaction" and includes the step a) of providing a mixture of a liquid sample and an "agglutinating reagent". Step f) refers to separation of "agglutinated material" from "non-agglutinated material". However, nowhere in the claim is it stated the components of the agglutination reaction are. Presumably, the agglutinating reagent is one of the components—what is the other? In order for an agglutination reaction to occur, a second component or material would be essential; such a second component is not recited in the claims.

It would also seem that the component to be agglutinated by the agglutinating reagent is contained in the liquid sample, but this is not clear. It is also unclear what the components of the

"agglutinated material" and the "non-agglutinated material". The claim fails to make clear that the agglutinated material is formed by an agglutination reaction between the agglutinating reagent and some component in the sample.

Response to Arguments

15. Applicant's arguments filed 9/18/07 have been fully considered.

16. With respect to the rejection of claim 21 under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, Applicant's arguments (see page 8, the third paragraph) have been considered but are not persuasive of error. Applicant argues that the other component of the agglutination reaction is the "liquid sample" but does not indicate where this is recited in the claim. It is maintained for reasons of record that the claim is incomplete since it fails to recite what the other component of the agglutination reaction is, since it is nowhere recited in the claim that the agglutination reagent agglutinates a component of the liquid sample in order to form agglutinated material.

Conclusion

17. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christine Foster whose telephone number is (571) 272-8786. The examiner can normally be reached on M-F 8:30-5. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached at (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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